DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993-0002

February 13, 2015

Biosafe, SA
Attention: Aurélie Piron
Regulatory Manager
Route du Petit Eysins
1262 Eysins (Vaud)
Switzerland

Re: BK140203
Trade/Device Name: SEPAX Cell Separation System and Single Use Kits
Regulation Number: 21 CFR 864.9900
Regulation Name: Cord blood processing system and storage container
Regulatory Class: Class II
Product Code: OAO
Dated: January 12, 2015
Received: January 14, 2015

Dear Ms. Piron:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CBER does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, ″Misbranding by reference to premarket notification″ (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research

Enclosure

Indication for Use

510(k) Number (if known): BK140203

Device Name: Sepax Cell Separation System and Single Use Kits

Indication For Use: The Sepax system is a cord blood cell processing system intended for laboratory use in exclusive combination with a compatible single-use separation kit supplied by Biosafe. The cord blood to be processed has been previously collected and transported to the laboratory by other means. The Sepax system allows the fast, automated and reproducible separations of cord blood. The Sepax system is not intended for use in transfusion applications at bedside, where blood circulates directly between a patient and the Sepax unit.